UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Biomedical Device Consultants & Laboratories of Colorado, LLC,

Plaintiff,

v.

TA Instruments – Waters, LLC,

Defendants.

Civil File No. 0:17-cv-03403

SUPPLEMENTAL DECLARATION OF MICHAEL GIRARD IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Michael J. Girard, hereby declare and state as follows:

1. I have been retained by Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC ("BDC") to offer technical analysis and opinions regarding various issues relevant to this action, including infringement and validity of the Patents-in-Suit, U.S. Patent Nos. 8,584,538 ("the '538 Patent"), 8,627,708 ("the '708 Patent"), 9,186,224 ("the '224 Patent"), 9,237,935 ("the '935 Patent") (collectively, the "Patents-in-Suit"). I have personal knowledge of the facts herein, and if called as a witness, I could and would testify competently thereto.

2. I submitted a declaration in this matter on November 22, 2017.

3. Since submitting my declaration, I have reviewed the materials filed by Defendant TA Instruments – Waters, LLC ("TA Instruments") in opposition to BDC's motion for preliminary injunction, including the TA Instruments opposition brief and the Declaration of Kristen Billiar and exhibits thereto.

A. The DuraPulse Infringes the ’935 Patent

4. After reviewing TA Instruments’ opposition, it is still my opinion that the DuraPulse infringes claims 1 and 9 of the ’935 Patent. Both of the elements that TA Instruments states are missing from the DuraPulse—a pressure source in fluid communication with the fluid distribution chamber and test system fluid under compression—are, in fact, present in the DuraPulse.

i. DuraPulse’s Pressure Source Is In Fluid Communication with Pressure Source

5. In its opposition, TA Instruments claims that it does not infringe the ’935 Patent because its DuraPulse device does not have a pressure source in fluid communication with the fluid return chamber. As evidence, TA Instruments notes that the DuraPulse has a drip guard that prevents test fluid from reaching its motor.

6. The presence of a drip guard does not alter my opinion that every limitation of claims 1 and 9 of the ’935 Patent is present in the DuraPulse.

7. The DuraPulse’s drive motor creates the force that ultimately pressurizes the test chamber, and therefore the drive motor is part of the pressure source. However, my opinion has never been that the “pressure source” of the DuraPulse is limited to only the drive motor. In my opening declaration, I merely noted that the “pressure source” was inside the base/cylinders of the DuraPulse. The drive motor is part of a larger assembly that forms the “pressure source” that includes at least a piston and some type of barrier to prevent test fluid from entering the drive motor, all contained within the base/cylinders of the DuraPulse.

8. That the DuraPulse uses a drip guard as the barrier does not alter the infringement analysis. In fact, the use of a barrier is specifically taught by the '935 Patent, which teaches using a "diaphragm 215" as the barrier. The drip guard is part of a larger system that includes a drive motor that drives a piston that is connected to one or more components that translate force from the motor to the test fluid within the cylinders. This larger system is the "pressure source." The point where this system contacts the test fluid is in the base or cylinders of the DuraPulse. The cylinders of the DuraPulse provide fluid communication between the base and fluid distribution chamber. Therefore, the "pressure source" is in fluid communication with the fluid distribution chamber.

ii. **DuraPulse's Test Fluid Is Put "Under Compression"**

9. TA Instruments also claims that the DuraPulse does not have a test system fluid that is ever "under compression."

10. The basis for this claim is that its test fluid is either deionized water or a phosphate buffered saline solution, both of which are "incompressible liquids."

11. Incompressible liquids cannot be compressed (absent very strong force). However, incompressible liquids can be placed "under compression." In other words, compressive forces can be placed on liquids. This is the principle behind the field of hydraulics and hydraulic systems: pressure is created and transmitted by placing compressive forces on incompressible fluids.

12. The plain meaning of "under compression" is not "compressed," as shown by TA Instruments' own expert's declaration. In Paragraph 76, Dr. Billiar interprets "under compression" to mean "under pressure." This is consistent with my

understanding of the plain and ordinary meaning of under compression. This is also consistent with the specification of the patent. When the test fluid is pressurized, the specification describes it as a "compression stroke." '935 Patent col.12, ll.4-6. Similarly, in the specification's discussion of the compliance chamber, it states: "a compliance chamber which provides a volume for holding a gas or an elastic material that *compresses under a pressure placed upon fluid* in the test chamber . . . ." '935 Patent col.2, ll.54-56. Therefore, the person of ordinary skill would understand that the plain meaning of "under compression" is that compressive forces are being placed on the test system fluid, i.e., it is under pressure.

B. TA Instruments' Inequitable Conduct Argument Misstates Content of ISO 5840

13. In its opposition brief, TA Instruments claims that BDC falsely claimed that the use of a compliance chamber in accelerated durability testing was entirely new. According to TA Instruments, this was false because Annex F of ISO 5840 discloses the use of the same type of compliance chamber as referenced in the '224 and '935 Patents. TA Instruments' expert Dr. Billiar, similarly claims in Paragraph 54 of her report that "the 2005 edition of ISO 5840 suggested the use of a compliance chamber in heart valve durability testing." The reference to a "compliance chamber" in Annex F, however, is a reference to a completely distinct type of compliance chamber.

14. As indicated by its title, Annex F provides instruction for testing of unstented valves, primarily in a non-accelerated context. Unstented valves have no frame, they are sewn directly into a patient's tissue (e.g., aorta or heart muscle). Human

tissue is "complaint," i.e., it is not rigid. The "compliance" of human tissue affects the performance of such a valve. Therefore, when such valves are tested they should be tested using mounts or holders that are also "compliant," i.e., non-rigid, as described in Annex F to more closely match human physiology. This is also true for durability testing of unstented valves: they should be tested in low compliant mounts.

15. A compliant mounting chamber, however, is an entirely different component with an entirely different function than the compliance chamber described in the Patents-in-Suit. Compliance chambers that provide system compliance by helping control pressure gradients are not mentioned in ISO 5840. Compliance chambers are commonly used in real-time pulsatile flow test systems to meet the requirements of ISO 5840 to mimic human physiology, but their use for accelerated durability testing to control pressure spikes have not been effective prior to the device described in the Patents-in-Suit.

16. Because a compliant mounting chamber is a different component with a different function than the compliance chamber described in the Patents-in-Suit, Annex F could not have been material to the Examiner's decision to allow the claims of the Patents-in-Suit. Annex F does not disclose the compliance chamber or excess volume area referenced in the Patents-in-Suit.

C. The '224 Patent and'935 Patent Are Valid

i. The '224 Patent Has A Sufficient Written Description

17. The application for the '224 Patent reasonably conveys to the person of ordinary skill that the inventors were in possession of a device that operated above 200

bpm. The application repeatedly uses the words "accelerated" or "fatigue" to refer to the device. A person of ordinary skill in the art would recognize that "fatigue" or "durability" testing is done on an accelerated basis, and that accelerated testing is done at a rate greater than 200 bpm.

ii. Swanson Does Not Anticipate the '935 Patent

18. TA Instruments and Dr. Billiar also contend that Swanson (U.S. Patent 4,546,642) discloses all claim limitations of claims 1 and 9 of the '935 Patent. I understand that a prior art reference anticipates a claim if that single reference discloses all limitations of the claim expressly or inherently.

19. Swanson was considered by the Patent Office during the prosecution and it was determined to fail to teach the invention as claimed. Nonetheless, Dr. Billiar claims that Swanson contains all elements of the claims, including an "excess volume area" and a "compliance chamber."

20. The element identified by Dr. Billiar as functioning as the excess volume area and compliance chamber (as described by the '935 Patent) is Swanson's bellows component. The bellows component, however, as a different operating principal compared to the excess volume area and compliance chamber described by the '935 Patent.

21. As described in the '935 Patent, the compliance chamber stores fluid and pressure when the system is under compression. The compliance chamber acts similar to a spring. It stores pressure from the fluid during the drive stroke of the system. Fluid is then released creating valve closing pressures during the return stroke of the drive

system.

22. In contrast, the system described by Swanson generates flows and pressures by the drive system compressing or expanding bellows on both sides of the valves. When the test valve is open the bellows on the outflow side of the test valve is expanding and pulling fluid through the valve, essentially creating a pressure vacuum. Although the bellows accumulates fluid volume, the pressure remains very low or negative without significant storage of pressure to cause valve closure. Instead, to accomplish valve closure, the drive system must compress the bellows to increase pressure, which happens when the motor turns the swash plate that compresses the bellows and reverse the flow of fluid in the system. This is similar to the operation of a see-saw, rather than a spring.

23. The system in Swanson would not solve the problem of undesirable pressure spikes. Such spikes are likely when the system is operated at an accelerated rate due to the rigid driving system and bellows in its configuration. It would be clear to a person skilled in the art that the bellows in Swanson does not function as the compliance chamber described in the ’935 Patent. The Examiner who issued the Notice of Allowance for the ’935 Patent must have come to the same conclusion.

24. The bellows in Swanson are also not an excess volume area. The concept of an excess volume area is that there is a volume area for test system fluid to occupy in response to the fluid being under compression that is in “excess” of the volume area occupied when not under compression. In the Swanson system, there is no “excess” to its volume area reactive to the fluid being under compression. Rather, the volume receiving the fluid is the same as the volume sending the fluid; the fluid conduits, chambers and

bellows are identical on each side.

I declare under the penalty of perjury that the foregoing is true and correct. Executed on January 8, 2018 in Lino Lakes, Minnesota.

/s/ Michael J. Girard
Michael J. Girard